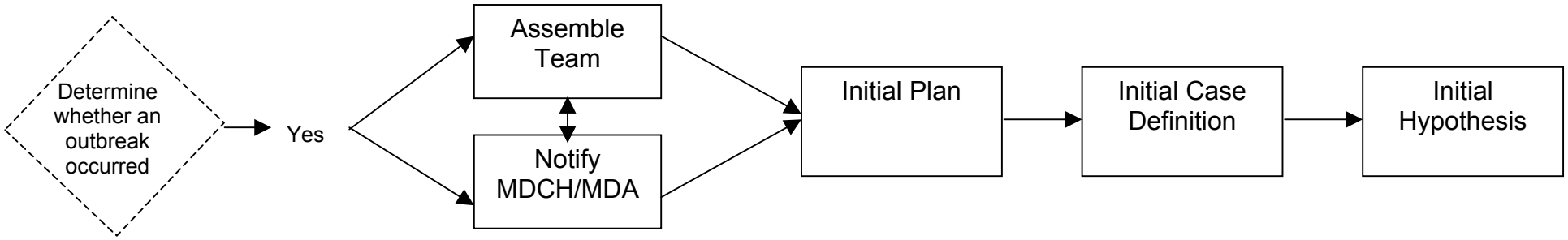
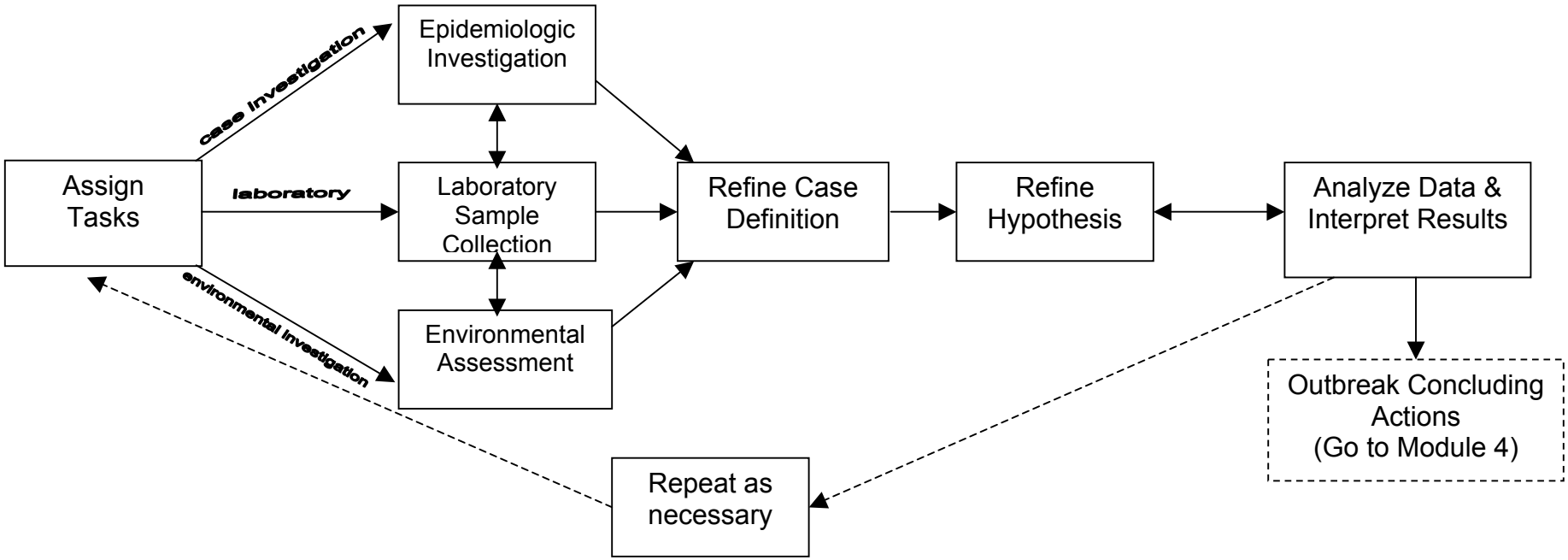
MODULE 3: OUTBREAK INVESTIGATION

STEP 1: Confirm Outbreak



STEP 2: Hypothesis Testing and Analytic Investigation *



* Initiate control actions as appropriate.

October 2001

I. Task List

Step 1: Initial Actions and Planning

A. Notify MDCH and MDA

B. Assemble Team

- ❑ Identify roles, responsibilities, and leadership for investigation.
  - Overall
  - Administration
  - Environmental
  - Communicable Disease and Epidemiology
  - Laboratory
  - Media and public communications
- ❑ Establish schedule for team meetings.

C. Review Available Information

- ❑ Summarize key information.
- ❑ Prepare for investigation – See Module 2 A.
- ❑ Take steps to verify diagnosis – See Module 2 B.
- ❑ Review or develop initial case definitions – See Module 2 F.
- ❑ Review or develop initial hypotheses – See Module 2 G.
- ❑ Confirm existence of outbreak – See Module 2 H.
- ❑ Identify additional information needed to test hypotheses.

D. Take Precautionary Control Action(s)

- ❑ Take immediate actions needed to prevent additional cases.
- ❑ Monitor to determine effectiveness of actions.

E. Develop Investigation Plan

- ❑ Develop method for finding additional cases (enhanced surveillance).

- ❑ Identify procedures to collect proper specimens - see Module 2: D and E, and Module 5.
- ❑ Determine study design and method of statistical analysis.
  - Cohort
  - Case-control
- ❑ Develop initial plan and timetable.
- ❑ Identify available resources (e.g., forms, equipment, personnel, media spokesperson).
- ❑ Obtain assistance (as needed).
- ❑ Inform lab of potential for sample submission (if not already done).

Step 2: Plan Implementation

F. Assign Tasks

G. Epidemiologic Investigation

- ❑ Implement plan for finding additional cases and controls.
- ❑ Interview identified cases and controls - See Appendix 15, Interviewing.

H. Laboratory Sample Collection

- ❑ See Module 5.
- ❑ Collect specimens using aseptic technique.
- ❑ Maintain chain-of-custody for samples.

I. Environmental Assessment

Planning Before Visiting the Site

- ❑ Determine scope and objective(s) of the site visit.
- ❑ Review available outbreak information (epidemiologic and laboratory findings).
- ❑ Review available facility information
- ❑ Review applicable sections of IAMFES manual (5^{th} edition).
- ❑ Review principles of effective interviewing

- ❑ Gather needed resources

On-site Data Gathering

Preliminary

- ❑ Meet with the facility manager(s) and consult with facility staff.
- ❑ Observe applicable food operations
- ❑ Review available records
- ❑ Collect environmental and/or food samples
- ❑ Draw/revise initial flow chart and diagram
- ❑ Implement actions (as needed) to stop the outbreak and/or prevent future reoccurrence.

Hazard Analysis

- ❑ Identify the on-site factors that contributed to the outbreak.
- ❑ Implement actions (as needed) to stop the outbreak and/or prevent future reoccurrence.
- ❑ Document your findings and immediately share with investigation team members and facility managers (as appropriate).

J. Collate Data

- ❑ Ensure completed questionnaires, environmental surveys, and other investigation data are turned in to designated person(s).
- ❑ Review for completeness and data quality.
- ❑ Take actions, as needed, to gather missing or incomplete data.
- ❑ Organize information by discipline (Epi, Lab, Environmental).

K. Analyze Data and Test Hypotheses

- ❑ Determine if analysis will be done by hand or using computer.
- ❑ If computer is used, initiate measures to ensure accurate and timely data entry.
  - Can use “Quick and Dirty” if a cohort study involving >20 cases

- ❑ Describe extent of outbreak by person, place and time (descriptive analysis) – See 2 G.
  - Epidemic curves
  - Frequency tables
  - Spot maps

- ❑ Conduct statistical tests to determine strength of associations
  - Chi Square
  - Fisher's Exact
  - Regression (Linear and Logistic)

- ❑ Calculate measures of association.
  - Cohort study – Relative Risk based on attack rates
  - Case-control - Odds Ratio based on odds

- ❑ Interpret results.

- ❑ Determine if hypotheses are confirmed or rejected.
  - If no association found, develop new hypotheses and identify information needed to test new hypotheses.

- ❑ Organize analyses in preparation for final report and CDC 52.13 form.

L. Repeat as Necessary

- ❑ Reanalyze data or gather additional information needed to test new hypotheses.

M. Concluding Actions

- ❑ Go to Module 4.

II. Task List Related Information

Step 1: Initial Actions and Planning

A. Notify MDCH and MDA

- Contact and coordinate with appropriate agencies from state contact list.
- May discover outbreak involves multiple jurisdictions or states.

B. Assemble Team

- ❑ Identify roles, responsibilities, and leadership for the investigation.
  - Overall
  - Administration
  - Environmental
  - Communicable Disease and Epidemiology
  - Laboratory
  - Media and public communications

The outbreak team may be assembled in order to help determine if an outbreak is occurring. Team structure may be different for each jurisdiction based on the local health department or district. While small outbreak investigations may be handled by one individual, large investigations can be very resource intensive.

Example 1:
An outbreak of Hepatitis A associated with frozen fresh strawberries began in March 1997 and extended into the next fiscal year. Total costs to the Calhoun County Health Department were estimated at over $368,000.

Multiple decisions need to be made quickly. Involve team members early and keep them updated.

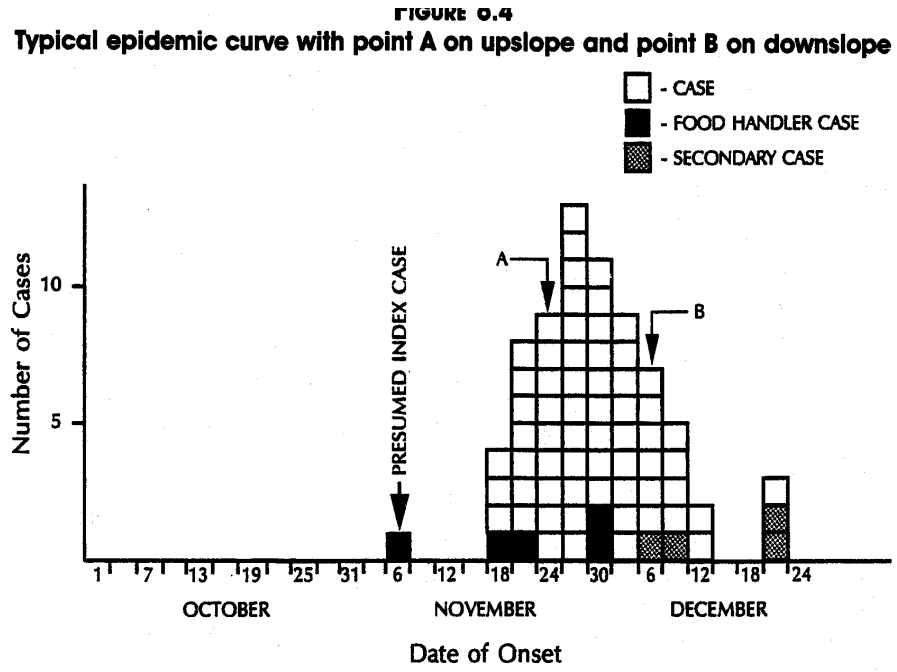
Outbreaks can occur on holidays and other times when key staff are out of the office. Do not rely on one person to do foodborne illness investigations. Cross training is critically important.

- Establish schedule for team meetings.
  - Outbreak team may need to meet multiple times a day initially and then decrease frequency as the situation stabilizes.

C. Review Available Information

- Summarize key information.
  - Concise, visual summaries help communicate information rapidly
    - line listings
    - initial epidemic curves

Example 2: Epidemic Curve



- Prepare for investigation – See Module 2 A.
- Take steps to verify diagnosis – See Module 2 B.
  - Check with lab and local providers for results of clinical and food samples, if taken.
- Review / develop initial case definitions – See Module 2 F.

Example 3: Case Definitions - Refresher

In an outbreak of bloody diarrhea and hemolytic-uremic syndrome early November 1990 caused by infection with *E. coli* 0157:H7 cases were defined in three classes:

Confirmed case: *E. coli* 0157:H7 isolated from a stool culture or development of hemolytic-uremic syndrome in a school-age child resident of the county with gastrointestinal symptoms beginning between November 3 and November 8, 1990.

Probable Case: Bloody diarrhea, with the same person, place, and time restriction.

Possible Case: Abdominal cramps and diarrhea (at least three stools in a 24-hour period) in a school-age child with onset during the same period).

- ❑ Review or develop initial hypotheses – See Module 2 G.
- ❑ Confirm existence of outbreak – See Module 2 H.
- ❑ Identify additional information needed to test hypotheses.
  - Interviews
  - Samples
  - Other (e.g., unique associations)

D. Take Precautionary Control Action(s)

- ❑ Take immediate actions needed to prevent additional cases.
- ❑ Monitor to determine effectiveness of actions.

E. Develop Investigation Plan

- The investigation should be coordinated by the LHD in whose jurisdiction the outbreak originated.
- Consider suspending or reassigning routine tasks for key investigators.

- Develop method for finding additional cases (enhanced surveillance).

  - Notify information providers (e.g., laboratories, health care providers, E.R.s) in your local network so they may be on alert – "increased index of suspicion".

    - Provide information on signs and symptoms of interest.

    - Advise regarding appropriate specimens to collect for diagnosis.

  - If outbreak involves a food establishment, ask management if others have called in to report illness.

  - If a private event (example: wedding reception), ask to receive list of those in attendance, along with their telephone numbers.

  - Credit card records are sometime useful.

- Identify procedures to collect proper specimens – see Module 2: D and E, and Module 5.

- Determine study design and method of statistical analysis.

  - Case-control

  - Cohort

  Note: No two outbreaks are the same – investigation methods need to be adapted to fit unique circumstances.

Signs or symptoms can help identify which agent(s) may be involved. Check IAMFES, "Control of Communicable Diseases Manual" or other reference for typical signs, symptoms and incubation periods of specific foodborne agents. Remember, this is only a guideline as not all organisms behave exactly as described in the book (e.g., incubation period and symptoms can vary). When the causative agent is known, consider using a specialized questionnaire that contains agent-specific information regarding signs and symptoms, usual methods of transmission. Examples:

- Hepatitis A

- *E. coli* 0157:H7

- Listeriosis

Statistical tests of outbreak data cannot be performed without gathering information from two groups:

- Cases: two or more ill persons with the same disease or syndrome who are associated by person, place or time.

- Controls: non-ill persons with the same characteristics of cases (therefore theoretically at risk for disease) - example: attended the event where the outbreak occurred.

  - Choosing appropriate controls is very important. Recommend consulting with epidemiologist.

    - Should be similar to cases except do not have the disease.

    - In restaurant situation, can select others who ate at the restaurant but did not become ill.

    - In community situation, can select controls in different ways:

      ⇨ Random digit dialing and select controls based on age, gender and being "free of disease"

      ⇨ Neighbors of cases or those with same phone extension

      ⇨ Patients from same physician practice or hospital who do not have the disease in question

      ⇨ Friends of cases

Selecting a study design:

- If outbreak involves a well-defined group of people with a shared exposure (e.g., persons at a single location, home, church, restaurant), select cohort study.

- If exposed group is not defined (cluster of *E. coli* 0157:H7 cases with the same PFGE pattern identified in southeastern Michigan during a two-week period), select a case-control study. In a case-control study, enroll a group of people with disease and a group of people without disease. Compare and contrast their previous exposures.

- Information on a case series is an acceptable alternative when:

  - There are insufficient numbers of cases to justify an analytical study (generally < 5), or

  - Controls are unavailable (e.g., everyone in the exposure group became ill)

Cohort Study

- Generally the best method for outbreaks involving a well-defined population.

Example 4: Cohort Study

1) Outbreak of gastroenteritis among those attending a wedding and a complete list of wedding guests was available.

2) Church or work potluck where the list of those in attendance is available.

3) Graduation party, if list of attendees available.

4) Anniversary or birthday party.

- Compute attack rates and relative risks, assessing the association between exposure (the food item) and disease (illness).

- To assess statistical significance, compute chi-square or Fisher Exact tests (for smaller studies when the number in any cell of a 2X2 table is 5 or less).

- Recommend use of "Quick and Dirty" program (based on Epi Info) if numbers are large enough. Generally need at least 20 persons to use this program.

Case-Control Study

- Compute odds ratio, to assess association between exposure (the food item) and disease (illness).

- To assess statistical significance, compute Chi-square or Fisher Exact tests (for smaller studies).

❑ Develop initial investigation plan and timetable.

- Address media relations and public information.

❑ Identify available resources (e.g., forms, equipment, personnel, media spokesperson).

❑ Obtain assistance (as needed).

❑ Inform lab of potential for sample submission (if not already done).

Step 2: Plan Implementation

F. Assign Tasks

G. Epidemiological Investigation

- ❑ Implement plan for finding additional cases and controls.
- ❑ Interview identified cases and controls – See Appendix 15, Interviewing for notes.
    - Assign persons from nursing, epidemiology and environmental health units, as needed, to do the interviewing.
    - Effective interviewing requires consistent and well-trained interviewers using the same questionnaire format.
    - The fewer the number of trained interviewers, the more consistent the data will be.
    - Provide interviewers with written statements to help kick-off interviews can increase uniformity. Example: "Hi, I'm _____ from _____ local health department."

H. Laboratory Sample Collection

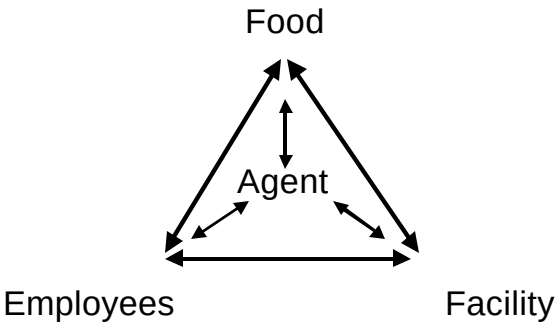
- ❑ See Module 5.
- ❑ Collect specimens using aseptic technique.
- ❑ Maintain chain-of-custody for samples.

I. Environmental Assessment

Background information

- Environmental assessments are not routine inspections.
    - Routine inspections assess compliance with existing legal requirements throughout the facility.
    - Environmental assessments:
        - Intensive and focused evaluations guided by outbreak information.
        - Regulatory action may be taken if legal standards are not met.

- Use a "systems approach" to assessment. Recognize that many variables interact to determine the safety of foods being produced.



  - Changes in one area can produce unintended changes in another.
  - Checklist type approach to evaluation can miss important interrelationships.

- A thorough environmental assessment may require repeat visits. Initial site visits may need to be conducted early in an outbreak investigation to:
  - Determine the risk of on-going unsafe food handling practices, and
  - Implement immediate corrective actions as needed.

- Involve the inspector or sanitarian that routinely inspects the facility.
  - They have an established rapport with the owner/managers.
  - They have detailed knowledge of the facility including products prepared or processed, manufacturing methods, hours and type of operation, past practices, and existing issues.

- Identify how the information gathered will be shared with:
  - Team members.
  - External agencies that may be interested in the outbreak investigation.
    - Key considerations include timeliness, format, and content of information to be shared.

<u>Planning Before Visiting the Site</u>

- Determine scope and objective(s) of the site visit.

  - Identify who will do facility evaluation. Invite public health nurse or epidemiologist to participate if available.

- Environmental assessments have multiple objectives.
  - Implement control actions to prevent additional cases in this outbreak.
  - Conduct hazard analysis to identify preventative measures to avoid future outbreaks.
  - Identify reasonable hypotheses for further investigation (typically during the very early stages of an investigation). Example: verify the specific foods sold by the facility.
  - Determine if any implicated food (or ingredient) is still present in the facility (for sampling, seizure, or hold as appropriate).
  - Systematic evaluation of potential hazards contributing to the outbreak.
    - source of microbiological contamination,
    - pathogen growth,
    - pathogen survival, or
    - effectiveness of steps intended to ensure pathogen destruction.
  - Assist other investigation team members (ex. collect menus or distribute stool sample kits to food workers when requested).

- Review available outbreak information (epidemiologic and laboratory findings).
  - Scope of assessment is determined by level of certainty of available information.
    - Targeted – evaluate methods used to prepare implicated food(s).
    - General – facility-wide evaluation (specific food/food group not yet implicated).
  - Timeline information is critically important.
    - Purchase date/time.
    - Consumption date/time.
    - Symptom onset date/time (for calculation of incubation period).
  - Focusing investigation on those foods implicated by the investigation will save resources.

  - Specific product descriptions
  - Specific purchase dates

- Review available facility information
  - Past inspection history and other records if outbreak involves an inspected food establishment.

- Review applicable sections of IAMFES manual (5th edition) for detailed guidance.
  - Information regarding on-site investigations is found on p. 20 – 44.
  - Information about the causative agent (if identified).
    - If agent is known, review foods or food groups frequently implicated in past outbreaks – Table B (p. 100 – 122).
    - Review the contributing factors identified from past outbreaks - Table B.
    - Determine if the primary host is human, animal or both.

Example 5: Differing Hosts for Foodborne Pathogens

Human Only	Animal or Human
Salmonella typhi	*Salmonella* non-typhi
Hepatitis A	*E. coli* 0157:H7
Shigella spp.	*Cryptosporidium parvum*
Enterotoxigenic *E. coli*	*Staphylococcus aureus*
Cyclospora cayetanensis	
Norwalk-like virus (NLV)	

Note: If hosts include only human beings, focus attention on evaluating human sources of contamination.

  - For chemical agents or toxin, review scientific literature to identify:
    - Known sources
    - Physical characteristics
    - Means of elaboration
  - Information about the implicated food(s):

- The contributing factors identified from past outbreaks involving that food group is summarized in several Keys (i.e. Tables) on page 133-140. There are different keys for:
  - Meat products – Key A
  - Poultry products – Key B
  - Milk products – Key C
  - Fish – Key D
  - Shellfish/crustaceans/marine mammals – Key E
  - Vegetables – Key F
  - Fruits/nuts/spices/grains/mushrooms - Key G, and
  - Mixed foods – Key H.

- Review principles of effective interviewing:
  - Interview = Directed and Purposeful Conversation
    - Interview all persons who worked directly with implicated food(s).
    - Pay attention to non-verbal cues and body language.
    - Consistency of information provided and reaction to clarifying questions.
  - Assess Communication Styles
    - Action – bottom line / “Just the facts”
    - Feeling – empathetic
    - Creative – need to see the big picture
    - Thinking – want all the details
  - Establish Rapport During Interviews
    - Identify yourself, your organization, and reason for investigation.
    - Inform individuals that multiple re-interviews may be needed.
    - Start with easy questions.

- Practice Effective Listening Skills:
  - Consider repeating the question and answer – both agree on what was said.
  - Avoid leading questions – "You didn't happen to eat the alfalfa sprouts, did you?"
- Food Worker Interviews:
  - Ask questions in chronological sequence to reconstruct timeline.
  - Let them tell their story.
  - When they cannot remember specific details:
    - Ask about typical work practices and routines.
    - Any unusual events or changes during time period?
    - Outbreaks frequently occur when process was "stressed". Example: busy day with too few staff.
  - Reword questions when needed information isn't provided or inconsistencies are identified.
  - Be persistent, patient, and respectful.
- Concluding the Interview:
  - Ask if individuals have unanswered questions or additional comments. May have information not previously considered.

❑ Gather needed resources:

- Assemble needed equipment and supplies:
  - Food or environmental sampling.
  - Temperature measuring devises.
- Assign sufficient staff - multiple tasks may need to be accomplished simultaneously.

<u>On-Site Evaluation</u>

Preliminary:

- Meet with the manager(s) and consult with facility staff:
  - Explain the reason for the visit.
    - Attempt to create a cooperative relationship.
    - Outline investigation objectives.
    - Review epidemiologic information:
      - Clarify the time period of interest.
      - Provide as exact description as possible of products under investigation:
        - ⇨ Lot codes and use-by dates for commercially processed foods (if available).
        - ⇨ This information can be used to identify the likely production lots that could have potentially involved, and
        - ⇨ The food workers who could have worked directly with the implicated foods.
  - Assess management:
    - Food safety knowledge (advanced, capable of learning, remedial).
    - Attitude.
    - Credibility of information being provided.
  - Gather relevant facility information to assess scope of the problem:
    - Collect menus for the meal(s) in question.
    - Quantity of food involved.
    - Approximate shelf life.
    - Determine if any of the suspect foods or ingredients are still on-site:
      - Potential for ongoing exposure.
      - Possibility of collecting samples.
  - Determine facility sick-leave policy and if manager was aware of ill food workers during that time period.

- Observe applicable food operations:
  - Initial walk through should follow implicated foods or food groups through the facility from start to finish.
  - Measure critical operations before they can be modified. Example: take temperatures.
  - Interview food workers:
    - Verify who worked directly with implicated foods.
    - Interview cross section of employees who span the firm's operations (owners, supervisors, and food workers) to determine if actual practices differed from SOPs during the period time period of interest.
    - Interview food workers without management being present.
    - Avoid relying on one employee's version.
    - If conflicting information is gathered, attempt to document each person's level of certainty regarding the information provided.
    - Obtain employee statements regarding their health and history of recent illness among relatives and friends.
  - Note differences from stated or written SOPs.
  - Use IAMFES forms G, H, and I (or similar locally developed forms) to document findings. Important information may include:
    - Ingredients used.
    - Sources of foods/ingredients.
    - Times and dates of deliveries.
    - Product rotation practices and inventory control.
    - Production times.
    - Steps in processing/preparation.
    - Equipment used.
- Review available records:

- SOPs – Management's intended procedures:
  - Employee health and hygiene policies.
  - Alternative procedures to bare hand contact.
  - Food safety training program.
  - Cleaning and sanitizing procedures.
  - Others
- Processing Records:
  - Review applicable records that are available:
    - Food processing records (e.g., time-temperature charts).
    - Quantities of food prepared.
    - Payroll records.
  - Some records (ex. recipes) may be "Commercial Confidential".
  - Industry may have legal right to refuse to share with need to know determined on case-by-case basis.

- Collect environmental and/or food samples:
  - Follow procedures outlined in Module 5 Laboratory Guidance in consultation with laboratory staff.
  - Gather samples while they are still available:
    - In-line.
    - Bracketing.
    - Finished product (frequently not available).
    - Ingredients (laboratories may be hesitant to test without sufficient epidemiologic evidence).

    Note: In-line and bracketing sampling is generally not necessary unless there is evidence of ongoing disease transmission.
  - Maintain chain of custody for all investigational samples:

- Conduct each investigation as though it might require legal action or end in litigation. The investigation must be able to pass legal challenges. Each local health department should develop and utilize a protocol for handling samples under a chain of custody. Parameters include authorized personnel, authorized equipment, record keeping and receipts, sample identification, temporary storage, transit and sign-off.

- Foods collected by regulatory authorities from the facility are "Official Samples".

- Samples of foods accepted from complainants have a higher potential for cross contamination and are considered as "Unofficial Samples".

- Document initial findings:

  - Draw/revise initial flow charts or diagrams:

    - Outline the stages of preparation for implicated foods based on best available information.

    - Visual summaries of information gathered from multiple sources.

  - Manager's perceptions:

    - Note the specific persons involved in preparation, handling, display, or service of implicated product(s).

    - Sick leave policy and persons known to have been sick or absent from work during the time period of interest.

  - Standard operating procedures (SOPs) and any deviations that occurred when the implicated product was produced:

    - Recipe of implicated food(s) containing multiple ingredients.

    - Inventory and rotation practices (e.g., first-in-first-out).

    - Degree of handling by food workers (e.g., bare hand contact with a ready-to-eat food).

  - Food worker interviews.

- Implement actions (as needed) to stop the outbreak and/or prevent future reoccurrence:

  - Clear recommendations with supervisor before taking action.

  - Options include:

- Employee or manager food safety training.
- Worker restriction or exclusion – see Appendix 6.
- Facility closure or menu limitation.
- Seizure, hold, or embargo implicated product.
- News Release - see Appendix 10, Communications.
- Administration of immune globulin - see Appendix 7, Hepatitis A.
- Initiate traceback investigation, if there is no evidence of onsite contamination – see Appendix 8.
- Recall (initiated by food manufacturer under guidance from regulators)

Hazard Analysis

- Identify the on-site factors that contributed to the outbreak:
  - Determine the likely source(s) of contamination, survival, growth or destruction (CSGD) of agents.
  - Food related factors:
    - Menu – listing of foods and beverages.
    - Food and water sources.
    - Quantities of food(s) produced:
      - identifying typical production practices, and
      - potential scope of the problem.
    - Ingredients – get them in writing.
    - Food intrinsic factors – physical characteristics and composition:
      - Acidity of foods (pH).
      - Water activity (a_w).
    - Environmental controls:

        - Time and temperature combinations.
    - Expected microbial content.
    - Intended use and consumers.
- Employee Health, Hygiene and Education:
    - Routine work practices (SOP).
    - Policies for sick workers.
    - Hand washing policies.
    - Employee traffic patterns.
    - Food safety education provided.
- Facility factors may include:
    - Design – Floor Plan.
    - Equipment design and maintenance.
    - Equipment location and use .
    - Food flow patterns.
    - Sanitation.
    - Food Product Segregation – adequate to prevent cross contamination?
    - Packaging.
    - Conditions of storage between packaging and use.
    - Processing methods (ex. “kill steps” designed to ensure destruction of microbiological agents):
        - Adequate as intended to be carried out?
        - Did something go wrong?

- Implement actions (as needed) to stop the outbreak and/or prevent future recurrence:
    - Same as discussed under preliminary on-site data gathering.

- ❑ Document your findings and immediately share with investigation team members:
  - Clearly communicate to facility manager(s) what actions they must take to prevent additional cases (e.g., use proper handwashing, monitor cooking temperatures).
  - Written reports are essential if your investigation is going to have impact beyond the actions that you take. Typical documentation includes:
    - Food flow chart
    - Facility flow diagram
    - Written reports
    - Sampling results
    - Other (example photographs)
  - See Module 4 C, Write Final Report & Submit CDC 52.13.
  - Factors that contributed to microbiological contamination, multiplication or survival must be reported on the CDC form 52.13.

J. Collate Data

- ❑ Ensure completed questionnaires, environmental surveys, and other investigation data are turned in to designated person(s):
  - It is important to forward information to proper individual(s) on timely basis:
    - For consistency.
    - For quality assurance.
  - Could be done by epidemiologist, clerk, nurse or sanitarian.
- ❑ Review for completeness and data quality.
  - Garbage in = garbage out.
- ❑ Take actions, as needed, to gather missing or incomplete data.
- ❑ Summarize information by discipline (Epi, Lab, Environmental).
  - Will help with report writing

K. Analyze Data and Interpret Results

- ❑ Determine if analysis will be done by hand or using computer.
  - Depends on number of cases and extent of analysis.
- ❑ If computer is used, initiate measures to ensure accurate and timely data entry:
  - Use "Quick and Dirty" if a cohort study involving > 20 cases.
    - Generates a basic analysis including:
      - Frequency tables.
      - Attack rates.
      - Relative risk estimates.
      - Tests for statistical significance.
    - Example of "Quick and Dirty" analysis output is at the end of this module.
  - Check accuracy, consistency, and completeness of submitted information.
  - Know the strengths and weaknesses of your data before entering it, "garbage in = garbage out".
  - Use the minimum number of trained data entry staff possible, preferably one or two persons.
  - Double check data after entry.
- ❑ Describe extent of outbreak by person, place and time (descriptive analysis) – See 2 G:
  - Epidemic curves:
    - Identify the number of generations of disease transmission that occurred during the outbreak.
    - Verify that there is no ongoing transmission of disease.
    - Disease transmission has likely stopped when the time period since date of onset of last case exceeds 1½ times the typical incubation period.
  - Frequency tables:
    - Demographics [population(s) involved, e.g., school aged children and adults working at schools].

- Symptomology (check consistency of symptoms among all cases).
- In cohort studies, calculate food specific attack rates.

Example 6: Using Attack Rates to Implicate a Food Item

- Would be high among those exposed to the (food) item.
- Would be low among those not exposed (not eating) the item.
- Difference between the exposed and unexposed attack rates is high.
- Most of the cases were exposed (ate the suspected food item), so that the exposure could "explain" most, if not all, of the cases.

Example 7: Attack Rates

TABLE 11–3 Food-specific Attack Rates Among Persons Attending a Church Supper, Oswego County, New York

Food or Beverage	Group A — Persons who ate specified food				Group B — Persons who did not eat specified food			
	Ill	Not Ill	Total	Attack Rate (Per cent)	Ill	Not Ill	Total	Attack Rate (Per cent)
Baked ham	29	17	46	63.0	17	12	29	58.6
Spinach	26	17	43	60.5	20	12	32	62.5
Mashed potato*	23	14	37	62.2	23	14	37	62.2
Cabbage salad	18	10	28	64.3	28	19	47	59.6
Jello	16	7	23	69.6	30	22	52	57.7
Rolls	21	16	37	56.8	25	13	38	65.8
Ice cream (van.)	43	11	54	79.6	3	18	21	14.3
Ice cream (choc.)*	25	22	47	53.2	20	7	27	74.1
Fruit salad	4	2	6	66.7	42	27	69	60.9

* One history indefinite as to consumption of mashed potato (#19), another as to chocolate ice cream (#44); both omitted from the tabulation.

From Centers for Disease Control: An Outbreak of Gastrointestinal Illness Following a Church Supper, Atlanta, July 1976.

How to Calculate Attack Rate

To compute the attack rate in percent, divide the number who became ill by the number who ate the food item and multiply by 100. (In the above example, baked ham 29 ÷ 46 x 100 = 63%). The offending food will show the greatest difference between the two attack rate percentages. The offending food should have a higher attack rate in "Group A" and a lower attack rate in "Group B". For example, in the table above, the attack rate for persons who ate vanilla ice cream (the offending food in the outbreak cited) was 80% while the attack rate for persons who did not eat vanilla ice cream was 14%. The disparity between the persons in "Group A" and "Group B" is the important point.

- Spot maps help define extent of the outbreak.
  - Is the outbreak confined to one jurisdiction?

- Conduct statistical tests to determine strength of associations.
  - Remember, lack of statistical significance does not always mean that illnesses were not foodborne

Statistical Evidence

Exposure	Disease +	Disease -	Total
+	3	0	3
-	0	1	1
	3	1	4

Fisher's Exact p value = .25

Statistical Evidence

Exposure	Disease +	Disease -	Total
+	6	0	6
-	0	2	2
	6	2	8

Fisher's Exact p value = .04

Statistical Evidence

Exposure	Disease +	Disease -	Total
+	9	0	9
-	0	3	3
	9	3	12

Fisher's Exact p value = .005

- Chi Square can be done by hand or computer.
- Fisher's Exact can be done by hand or computer.
- Regression (Linear and Logistic) - requires computer software

❑ Calculate measures of association:

- Cohort study – Relative Risk based on attack rates.
- Case-control – Odds Ratio based on odds.

❑ Interpret results.

❑ Determine if hypotheses are confirmed or rejected.

- If no association is found, develop new hypotheses and identify information needed to test new hypotheses.

❑ Organize analyses in preparation of final written report and CDC 52.13 form.

L. Repeat as necessary

❑ Re-analyze data or gather additional information needed to test new hypotheses.

M. Concluding actions

❑ Go to Module 4.

Distribution of age among all respondents

AGE	Freq	Percent	Cum.
21	1	2.9%	2.9%
22	2	5.7%	8.6%
23	4	11.4%	20.0%
24	3	8.6%	28.6%
25	3	8.6%	37.1%
26	2	5.7%	42.9%
27	3	8.6%	51.4%
28	2	5.7%	57.1%
29	1	2.9%	60.0%
30	1	2.9%	62.9%
33	1	2.9%	65.7%
34	3	8.6%	74.3%
35	5	14.3%	88.6%
36	1	2.9%	91.4%
37	2	5.7%	97.1%
39	1	2.9%	100.0%
Total	35	100.0%	

Total	Sum	Mean	Variance	Std Dev	Std Err
35	1011	28.886	29.692	5.449	0.921

Minimum	25%ile	Median	75%ile	Maximum	Mode
21.000	24.000	27.000	35.000	39.000	35.000

Table 4
Frequency of Nausea among those who were ill

Current selection: ILL="Y"

NAUSEA	Freq	Percent	Cum.
+	9	64.3%	64.3%
-	5	35.7%	100.0%
Total	14	100.0%	

Table 5
Frequency of Vomiting among those who were ill

Current selection: ILL="Y"

VOMITING	Freq	Percent	Cum.
+	3	21.4%	21.4%
-	11	78.6%	100.0%
Total	14	100.0%	

Table 6

Frequency of Abdominal Cramps among those who were ill

Current selection: ILL="Y"

ABDCRAMPS	Freq	Percent	Cum.
+	11	78.6%	78.6%
-	3	21.4%	100.0%
Total	14	100.0%	

Table 13
Incubation time (in hours) among those who were ill

Current selection: TIMESYMPTO>0

INCUBATION	Freq	Percent	Cum.
10.0	1	7.1%	7.1%
11.0	1	7.1%	14.3%
24.0	7	50.0%	64.3%
25.0	2	14.3%	78.6%
26.0	2	14.3%	92.9%
34.0	1	7.1%	100.0%
Total	14	100.0%	

Total	Sum	Mean	Variance	Std Dev	Std Err
14	325	23.214	35.874	5.989	1.601

Minimum	25%ile	Median	75%ile	Maximum	Mode
10.000	24.000	24.000	25.000	34.000	24.000

Student's "t", testing whether mean differs from zero.
T statistic = 14.502, df = 13 p-value = 0.00000

Table 14
ATTACK RATES BY ITEMS CONSUMED

EXPOSURE	TOTAL EXPOSED	ATTACK RATES EXPOSED	UNEXPOSED	DIFFERENCE
ITEM1	15	73%	15%	58%
ITEM2	15	33%	45%	-12%
ITEM3	19	26%	56%	-30%
ITEM4	16	44%	37%	7%
ITEM5	17	29%	50%	-21%
ITEM6	14	29%	48%	-19%

Table 15
Analysis of Food Item 1

ITEM1	ILL +	ILL -	Total
+	11	4	15
-	3	17	20
Total	14	21	35

Single Table Analysis

Odds ratio	15.58
Cornfield 95% confidence limits for OR	2.29 < OR < 130.18*
*May be inaccurate	
Maximum likelihood estimate of OR (MLE)	14.01
Exact 95% confidence limits for MLE	2.34 < OR < 119.29
Exact 95% Mid-P limits for MLE	2.80 < OR < 90.58
Probability of MLE >= 14.01 if population OR = 1.0	0.00070892
RISK RATIO(RR)(Outcome:ILL=+; Exposure:ITEM1=+)	4.89
95% confidence limits for RR	1.65 < RR < 14.50

Ignore risk ratio if case control study

	Chi-Squares	P-values	
Uncorrected:	12.15	0.00049015	<---
Mantel-Haenszel:	11.81	0.00059054	<---
Yates corrected:	9.84	0.00170410	<---